Health Policy 102 (2011) 200–213

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Review

Assisted reproductive technologies: A systematic review of safety and effectiveness to inform disinvestment policy

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ARTICLE INFO

Keywords:
Review, systematic
Reproductive techniques, assisted
Health policy
Disinvestment

ABSTRACT

Objective: Health policy relating to assisted reproductive technologies (ART) has been variably informed by clinical evidence, social values, political and fiscal considerations. This systematic review examined key factors associated with specific benefits and harms of ART to inform the development of a model for generating policy recommendations within an Australian disinvestment research agenda.
Methods: Six databases were searched from 1994 to 2009. Included articles contained data on safety and/or effectiveness of in vitro fertilisation (IVF) or IVF with intracytoplasmic sperm injection with reference to female age, male age or cycle rank. Narrative descriptions of key outcomes (live birth, miscarriage) were constructed alongside tabular summaries.
Results: Sixty-eight studies and one registry report were included. There was substantial heterogeneity present within the evidence-base which limited the strength and scope of conclusions that could be drawn. However, this review does affirm the differential effectiveness associated with the ageing of ART patients with regard to live birth and miscarriage.
Conclusion: From the available evidence, it was not possible to determine an explicit age or cycle rank that could be used to formulate defensible policy responsive to identified differential effectiveness. Stakeholder interpretation of this evidence-base may assist in developing policy that can incorporate uncertainty and reflect social values.

1. Introduction

Assisted reproductive technologies (ARTs) have been the source of significant social, medical and political debate over the past forty years, during which time they have become well established, broadly accepted and increasingly utilised. However, with this have come increasingly complex questions about how best to structure public health policies to guide the distribution of public funding within the domain of fertility care; these are yet to be clearly resolved.

1.1. Public subsidy of ART: Australian policy history and international comparisons

With 3.1% of babies born as the result of ART treatment [1], Australians utilise a high number of ART cycles per million population when compared to other countries [2]. This may be partly attributable to Australia's essentially

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doi:10.1016/j.healthpol.2011.07.007

unlimited public subsidy for ART services, which contrasts with other similarly developed countries.

For example, England's National Institute for Health and Clinical Excellence (NICE) currently recommends three cycles of treatment with full public funding for women aged 23–39 with a three year history of infertility [3]; however, implementation of this guidance across Primary Care Trusts has been variable and this guidance is currently under revision [4]. New Zealand has offered full public funding for two cycles since 2005, contingent on meeting strict social and medical criteria [5]. At the time of writing, Canada's funding situation is in a state of flux; funding was once only offered for bilaterally occluded fallopian tubes (Ontario) or as a partial tax credit (Quebec) [6]. However, Quebec has recently introduced funding for three cycles of treatment while Ontario and Alberta have commissioned reviews of funding for these procedures. In contrast to these more restrictive policies, Israel employs full public subsidy for unlimited cycles of treatment for women aged 18–45 until two children are born from a relationship [7].

These disparate international funding policies have translated into highly variable numbers of annual treatment cycles performed in each country per million population, ranging from 292 (Canada), 614 (UK), 710 (NZ), 1568 (Australia), to 3688 (Israel) [2]. These utilisation statistics are likely to change following the introduction of new funding policies in these jurisdictions.

Each country has its own social, political and medical history of ART funding which has shaped resource allocation. This complex interplay of factors has created unique funding scenarios internationally, and provides a multifaceted environment in which to consider the development of approaches to disinvestment within an Australian research project. Disinvestment seeks to improve quality of care and health outcomes by evaluating existing health services; identifying those that do not provide safe, effective or cost-effective care; and redirecting funding away from these services toward those with superior safety, effectiveness and/or cost-effectiveness profiles [8]. The evidentiary requirements for these processes are yet to be defined.

Australia has offered public subsidy of ART since 1990 through the universal health insurance program, Medicare. Australian citizens and permanent residents are eligible for this subsidy regardless of their age or any prior treatment attempts, provided that they meet State-based legislative requirements. However, as ART in Australia are offered primarily through the private sector, there remains a variably-sized patient-borne 'gap' payment. As such, ART are also covered under the Medicare Safety Net, which can be accessed once an individual's out-of-pocket medical expenses reach a threshold amount in a given year, reducing any further out-of-pocket medical expenses in that period.

Mirroring the international experience, the public subsidy of ART has been a perennially contentious health policy issue in Australia. The Australian government – regardless of the party in power at the time – has periodically entered into policy debates around access criteria for ART services. The use of clinical evidence in these policy debates has been highly variable; while some policy decisions have ostensibly been based on clinical evidence, others have claimed to be based on fiscal rationales and some appear to have been primarily politically motivated.

During the 1980s, use of ART increased, and attracted greater attention. Despite this, the services were not officially subsidised by Medicare at this time. Many components of the procedures could, however, be claimed under existing funding arrangements for established gynaecological procedures [9]. Recommendations from a 1985 government review were to not provide specific funding for ART. The review concluded "Medicare benefits are inappropriate for IVF at the present time" as "IVF should still be regarded as being in a development phase" [9]. However, pro-IVF lobby groups – coalitions of consumers and clinicians – successfully mobilised an "electorally significant" [10] force of opinion for Government funding of ART, and political pressure saw specific items for ART listed for public subsidy in 1990, with a lifetime limit of six stimulated cycles.

In 1996, financial pressure from "limited resources" [10] led the Government to introduce a 10% overall reduction in base subsidy for ART procedures. The same Government subsequently removed the six-cycle limit in 2000 to create an unlimited public subsidy. This, arguably, was a utilisation reflected decision: very few women were undertaking more than six cycles of treatment [11], hence the removal of this restriction would have little financial impact while hopefully silencing the vocal pro-IVF lobby groups.

In 2005, the Australian government commissioned a review of ART clinical outcomes, focussed on safety, effectiveness and cost-effectiveness. Before the official government response was released, the Health Minister created controversy by suggesting that the 2005/2006 budget would include limits to public subsidy: women aged under 42 would be eligible for three stimulated cycles of treatment per year, and women aged over 42 would be eligible to access subsidy for a total of three stimulated cycles [12]. These limits reflected some of those in place in a number of European and other international jurisdictions, but were attacked by interest groups as discriminatory, potentially dangerous and stressful for women [13]. The limits were not enacted and existing funding arrangements were maintained [14], despite the review suggesting an upper age limit for treatment, amongst other considerations. In this instance, political considerations were clearly more influential than the clinical evidence-base and funding precedents set by other countries.

Five years later, the 2009/2010 budget introduced a cap on the amount of rebate claimable under the Extended Medicare Safety Net (EMSN) for ART in an attempt to limit the Government's financial liability for these services. This was stated to be in response to evidence that introduction of the EMSN had seen demand for ART increase substantially, but that the government's additional spending on these benefits had not been accompanied by a reduction in the out-of-pocket expenses of patients, as specialists had been increasing their fees [15,16]. The EMSN had been designed to support patients with high out-of-pocket expenses; however, an independent review of its effectiveness suggested that the extra money being paid by government was being directed toward provider income rather than reduced costs for patients. It was estimated that